Attorney Docket No. 9450-13DV Application Serial No. 10/814,972 Filed: March 30, 2004

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REMARKS

This response is in reply to the Office Action dated August 1, 2008 ("the Action"). Applicant hereby requests further consideration of the application in view of the amendments above and the comments that follow. Claims 1-45 are pending in the application.

I. Claim 45

The Action has withdrawn Claim 45 from consideration as being directed to a non-elected invention, *e.g.*, a connector -- not a guidewire. Independent Claim 1 is directed to a guidewire and independent Claim 25 is directed to a medical cable. Claims 42 and 44 depend from Claim 25 and each recite features similar to those found in Claim 45. Applicant has amended Claim 45 to recite the connector in combination with a guidewire or medical coaxial cable. Accordingly, Applicant respectfully requests that Claim 45 be maintained in the instant application as being sufficiently related to the pending claims as to not cause any undue hardship on the Examiner to maintain this claim in the instant application. Support for Claim 45 can be found, *inter alia*, at pp. 27-28 of the specification.

II. Claim Objections

The Action objects to Claims 2 and 16 for claim informalities. Applicant has amended Claim 2 to obviate the antecedent basis issue for the term "the lumen". Applicant has amended Claim 16 to recite that the guidewire comprises a material that is sterilizable to clarify what structure or feature limitation is claimed.

The Action objects to Claim 24 for being of improper dependent form and because it is unclear how Claim 24 further limits any of the features listed in Claim 23. Claim 24 has been amended to recite that the guidewire is releasably engageable to a connector a plurality of times over an interventional procedure to allow different medical devices to be loaded onto and removed from the guidewire (as described, for example, at p. 8, lines 7-22, of the pending

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application) and that the connector includes a wiper to inhibit the introduction of fluids into the connector (*see*, p. 23, lines 5-19, of the pending application).

III. The §112, First Paragraph Rejections

At paragraph 6 of the Action, the Action rejects Claims 1-44 as allegedly failing to comply with the written description requirement because the specification "fails to disclose wherein the guidewire, connector, or guid[e]wire and connector combination comprises an identification parameter that is at least one of the following: an electrical circuit, a mechanical configuration, optical or visual indicia, whereby the identification parameter allows assembly only for a suitable connector and guidewire combination (Action, p. 3). Applicant respectfully disagrees.

As a preliminary matter, Applicant notes that the identification parameter feature is only recited in some of the pending claims (e.g., Claims 23, 30, 32, 37 and 38), and it is improper to reject all the pending claims based on this feature being included in only a small subset of the pending claims. Applicant respectfully requests that this rejection be withdrawn for Claims 1-22, 24-29, 31, 33-36, and 39-44, which clearly do not include this recitation.

Further, Applicant respectfully directs the Examiner's attention to page 28 of the specification, which describes identification systems to help ensure that the proper guidewire/cable and connector combination is used. However, Applicant has amended the affected claims to more literally correspond with the text in the application to advance prosecution.

IV. The §112, Second Paragraph Rejections

Paragraphs 7-8 of the Action reject Claims 1-44 under §112, second paragraph, for allegedly being indefinite for failing to distinctly claim the subject matter which Applicant claims as the invention. Applicant believes that the rejection of Claims 1 and 25 at paragraph 9 of the Action is intended to provide the particular basis for this §112, second paragraph for all of Claims 1-44. It this assumption is incorrect, Applicant respectfully requests that the

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Action be re-issued with a more particular basis of rejection so that Applicant can address the issue.

At paragraph 9, the Action rejects Claims 1 and 25 for the recitation of "shaped for insertion into a connector" as the Action opines that it is unclear as to whether the connector has been positively set forth. Applicant has amended these claims to more positively recite this feature to obviate this rejection and positively set forth the connector feature. Accordingly, Applicant respectfully requests that these rejections be withdrawn.

V. The Connector Combination Claims

At paragraph 10, the Action states that Claims 23, 27-32, 34-36 and 39-44 are directed to the connector, but were not given patentable weight. The Action then states that any amendments to include the connector in "the claimed invention" would raise issues regarding election by original presentation (Action, p. 4). This warning appears to indicate that the amendment to clarify the claims required under paragraph 9 (*see* para. IV above), now might raise issues regarding election by original presentation. Applicant respectfully disagrees.

The connector has always been recited in Claims 1 and 25. Further, and notably, one or more of the prior Office Actions searched, examined and considered the dependent connector claims. For example, the Action mailed 2/14/08 searched and examined various connector claims. Applicant respectfully submits that the connector recitations DO NOT raise issues regarding election by original presentation. Applicant respectfully requests that the present Examiner consider these claims, as did the predecessor Examiner.

VI. The Anticipation and Obviousness Rejections

The Examiner rejects the pending claims as being anticipated by or obvious over U.S. Patent No. 5,792,055 to McKinnon ("McKinnon").

More particularly, the Action rejects Claims 1-4, 9-12, 16-23 and 25-44 as being anticipated by McKinnon. The Action alleges that McKinnon discloses a MRI guidewire (abstract) with an inner (center) conductor 13, an outer conductor 15, with a distal end sized and shaped to receive MRI signals (Figure 1) and a proximate end sized for insertion into a connector (col. 4, lines 54-65, Figure 1). The Action concedes that McKinnon fails to teach

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the use of a connector but alleges that it is inherent to use a connection means to connect a guidewire to a control station and that such includes an insulated area between the inner and outer conductor 14, and that the guidewire is connected to the MRI scanner and circuits (Figure 1). Applicant respectfully disagrees. Applicant agrees that some type of connection must have been contemplated by McKinnon, but it is unclear what such a connection means was used.

The Action also alleges that McKinnon describes a proximal guidewire configuration where the inner conductor extends beyond the outer conductor (citing to col. 4, lines 57-66 and col. 5, lines 1-27, Figures 1-3). Again, Applicant respectfully disagrees.

Figure 2 illustrates <u>a distal end of the guidewire</u> with the inner conductor 13 shown extending beyond the shield 15 and the supporting text indicates that the proximal end <u>is not shown</u> (col. 4, lines 62-63). McKinnon fails to teach or suggest a guidewire with the proximal end inner conductor contact <u>having an electrically conductive material disposed at least partially around the inner conductor</u>. Applicant is restating hereinbelow independent Claims 1 and 25 for ease of discussion.

1. A magnetic resonance imaging (MRI) guidewire, comprising: a connector having a non-magnetic body;

a guidewire having a distal end sized and shaped for insertion into a subject and a proximal end being sized and shaped for insertion into the connector, the guidewire having an inner conductor extending at least a major length of the guidewire and an outer conductor coaxially disposed about the inner conductor extending at least a major length of the guidewire;

the proximal end of the guidewire having:

an outer conductor contact coupled electrically to the outer conductor; and

an extended section of the inner conductor that extends axially beyond the outer conductor contact, the extended section including:

an inner conductor contact having an electrically conductive material disposed at least partially around the inner conductor; and

an insulated area interposed between the outer conductor contact and the inner conductor contact, and having an electrically insulating material disposed at least partially around the inner conductor;

wherein the distal end of the guidewire defines an antenna configured to

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detect MRI signals and the inner and outer conductors are configured to conduct the detected MRI signals to the proximal end of the guidewire.

25. An MRI compatible medical coaxial cable, comprising: a connector having a non-magnetic body;

the coaxial cable having opposing proximal and distal ends with the proximal end sized and shaped for insertion into the connector, the coaxial cable having an inner conductor extending at least a major length of the coaxial cable and an outer conductor coaxially disposed about the inner conductor and extending at least a major length of the coaxial cable,

wherein the proximal end of the coaxial cable has:

an outer conductor contact coupled electrically to the outer conductor; and

an extended section of the inner conductor that extends axially beyond the outer conductor contact, the extended section including:

an inner conductor contact having an electrically conductive material disposed at least partially around the inner conductor, wherein the inner conductor contact and the inner conductor define a diameter that is greater than a diameter of the inner conductor residing under the outer conductor; and

an insulated area positioned to isolate electrically the outer conductive contact from the inner conductive contact, and having an electrically insulating material disposed at least partially around the inner conductor,

wherein the coaxial cable is configured to conduct MRI signals from a distal end portion to the proximal end.

Thus, Applicant submits that Claims 1 and 25 are patentable over the cited art for at least the emphasized features. Further, Applicant directs the Examiner's attention to amended claims 2 and 25 which further recite that the inner conductor contact is configured so that the conductor electrically conductive material increases the diameter of the inner conductor relative to a diameter of the inner conductor under the outer conductor. (See, e.g., Figure 1 of the instant application). See also, Claims 17-22, which are directed to particular configurations of the inner/outer conductors that are independently patentable over the cited prior art. For example, Claim 17 recites that the outer conductor contact and the inner conductor contact are each annular in shape. Claim 18 recites that the outer conductor contact and the inner conductor contact have approximately equal diameters. Claim 22 recites an

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attachment extension. Applicant respectfully submits that these claims are patentable over McKinnon and the secondary references.

Further, McKinnon describes an open wire length antenna with the proximal end of the coaxial cable for "connection to the standard antenna input of control station 12" (col. 4, lines 63-65, referring to Figure 1). McKinnon also states that the medical appliance 9 inserted into the subject is connected via conductor 10 to control station 12 and states that such a general configuration is familiar to those of skill in the art and will not be described(col. 4, lines 50-53). McKinnon also states that the "coaxial cable is adapted to connection to the antenna input" (Col 5, line 8) and that the connection is with "wire with appropriate polarities arranged for connection thereof to the antenna" Col 5, line 26). Applicant was unable to find a context or meaning of connection referring to the actual device of a "connector", nor is "connector" mentioned. In addition there are no figures depicting any "connectors".

Notably, not only is there no mention of connectors, there is clearly no teaching or suggestion of the use of a detachable connector as opposed to a permanently affixed connector as recited in some of the pending claims (see, e.g., Claims 10, and 23-24, 28). That is, some embodiments of the instant invention provide a detachable connector that can easily be attached and detached to allow different surgical tools to be guided into position.

In addition, embodiments of the invention allow the connection to the MR scanner in a rapid manner. This is because once the guidewire is in position inside the body (i) it should not be moved while it is used to guide the catheter; and (ii) according to some embodiments of the present invention, to facilitate a rapid connection, the connector can be configured to be fast to permit switching between different types of catheters (*e.g.*, for biopsy and therapy delivery). Twisting the connector/rotating the guidewire risks relocating the tip so that the positioning procedure may need to be repeated. Thus, using a conventional twist type RF connector on the MRI antenna guidewire would appear to severely limit, if not eliminate, its functionality as a guidewire at least from the perspective of attachment/detachability as contemplated by some particular embodiments as noted above (*see, e.g.*, Claims 10, 23-24, 28). Thus, Applicant submits that Claims 10, 23-24 and 28 are patentable over the cited art

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for at least these additional reasons.

Applicant respectfully submits that the connector configurations described by embodiments of the instant invention and as claimed overcome the deficiencies of the prior art and that the pending claims are patentable over McKinnon.

CONCLUSION

Accordingly, Applicant submits that the present application is in condition for allowance and the same is earnestly solicited. Should the Examiner have any matters outstanding of resolution, he is encouraged to telephone the undersigned at 919-854-1400 for expeditious handling.

Respectfully submitted,

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CERTIFICATION OF TRANSMISSION

I hereby certify that this correspondence is being transmitted via the Office electronic filing system in accordance with § 1.6(a)(4) to the U.S. Patent and Trademark Office on October 29, 2008.

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